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February 22, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

DOCKET NO. 99N-4784 WRITTEN COMMENTS

Proposed Rule: Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent
Premarket Notification

The above Proposed Rule regarding redaction of substantially equivalent 510(k)s is a reasonable alternative to the current procedure. However, there is one area that I believe has not been addressed.

Under Section II (Procedure Amendments) of the Proposed Rule, the redacted version of a 510(k) is to be provided to the FDA by the Applicant within 30 days of SE determination, and is to be in a format "that can be immediately released . . . to the public."

Under the current procedure, the Applicant receives a copy of the PMN file from the FDA for review and redaction. This copy includes the submission to, and correspondence with, the FDA. Also included in this copy are any notes, forms, memos or comments created by the reviewer or other FDA staff. The Applicant has the opportunity to delete appropriate confidential information from the entire file, including documents originated by the FDA.

Under this Proposed Rule, who will review all documents in a 510(k) file that the Applicant has not seen? Who will take responsibility as to the accuracy of the redaction decisions? Under this Proposed Rule, the Applicant would not be aware of these redaction decisions until after the information has been published.

Thank you for the opportunity to comment on the above proposal.

Sincerely,

Jean Stenger

Jean Stenger
Regulatory Affairs Associate

99N-4784

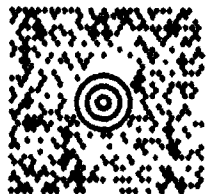
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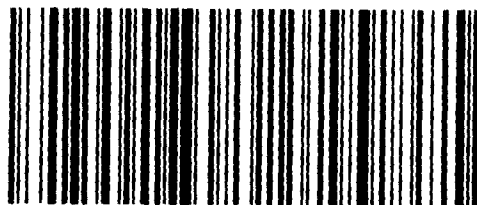


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